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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,492	03/21/2001	Mark A. Labow	4-31360A/USN	2101

1095 7590 10/22/2002

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/22/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/813,492

Applicant(s)

LABOW ET AL.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) 3-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1642

### DETAILED ACTION

1. Applicant's election without traverse of Group 1, claims 1 and 2 in Paper No. 8 (filed July 30, 2002) is acknowledged.

Claims 1-5 are pending.

Claims 3-5, drawn to non-elected inventions, are withdrawn from consideration.

Claims 1 and 2 are examined on the merits.

#### *Claim Rejections - 35 USC § 112*

2. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of detecting breast tumors comprising using probes that comprise SEQ ID NO: 1 or probes that consist of fragments of SEQ ID NO: 2, does not reasonably provide enablement for the full scope of detecting any type of tumor, and methods that comprise providing probes that comprise fragments of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the

Art Unit: 1642

relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See *Ex parte Forman*, 230 USPQ 546, BPAI, 1986.

Claims 1 and 2 are drawn to methods for detecting any type of tumor. The methods of claims 1 and 2 comprise providing a probe that comprises either the nucleic acid sequence of SEQ ID NO: 1, or comprises a fragment of SEQ ID NO: 1. Thus, to the extent the claims read on methods of detection using probes that comprise a fragment of SEQ ID NO: 1, the specification fails to provide adequate guidance for how to make and use the claimed methods.

The specification teaches one example of a probe that may be used in a method for the detection of breast tumors. The probe comprises the sequence of SEQ ID NO: 1 or consists of fragments of SEQ ID NO: 1. The specification fails to teach any other examples of useful probes, and fails to teach that detection of hybridizing nucleic acids to these probes is associated with any type of cancer. Thus, the scope of the teachings of the specification is not commensurate in scope with that of the claims. Furthermore, the specification fails to provide guidance for how to make other useful probes, and fails to show that differential detection of hybridizing nucleic acids in breast tumors may be extrapolated to methods for the detection of any type of tumor. Because the relationship between a cancers and the expression of mRNA species is not predictable, it is not possible for one of skill in the art to extrapolate the findings in the specification concerning the detection of breast tumors with the ability to detect tumors other than breast tumors. Thus, the specification merely presents of wish or hope to establish such a relationship, but fails to provide a reasonable expectation that claimed methods would be useful the detection of any tumor other than a breast tumor.

Because of the broad scope of the claims that is not commensurate in scope with that of the disclosure of the specification, and in view of the unpredictability of tumor diagnostics, undue experimentation on the part of one skilled in the art would be necessary to practice the full scope the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being rejected by Papsidero (U.S. 6,306,653; issued Oct. 23, 2001; filing date Sep. 3, 1998).

Papsidero teaches a nucleic acid sequence (SEQ ID NO: 11) that comprises a fragment of SEQ ID NO: 1, where the fragment is at least about 10 nucleotides (see enclosed alignment). Papsidero teaches the use of the nucleic acid probes from the nucleic acid sequence that may be used in the detection of breast cancer (col. 3, lines 6-25, col. 18, line 58- col. 20, line 28, col. 31, line 64 – col. 33, line 66). Thus, Papsidero teaches methods that are the same as that claimed.

Art Unit: 1642

*Conclusion*

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892.

Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran  
Patent Examiner  
October 21, 2002

  
ANTHONY G. CAPUTA  
SUPERVISOR, PATENT EXAMINER  
TECHNOLOGY CENTER 1800

## ORIGIN

Query Match 17.9%; Score 361.8; DB 6; Length 472;

Best Local Similarity 99.2%; Pred. No. 3.7e-73;

Matches 374; Conservative 0; Mismatches 2; Indels 1; Gaps 1;

Qy 1633 agcgggtggtccagatgctcttgagggtgataatgagacacagagcagcagc 1692  
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 Qy 1693 tccataggttaaaty-ccacacaaatggtccttgcctatccctcattgactt 1751  
 Db 411 TCCATAGGTAAATGCCCCAACCAACTGGCTTGGCTTAATGCCCTCATGATTTT 352  
 Qy 1752 agcattatattatatttccctgacattctgcagccttgatttattccact 1811  
 Db 351 GGCATTTAATTTATTTATTTCTGACATTTCTGCAAGCTTTGATTTATTTCCACTT 292  
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 Db 291 TATAGATGAGGAATTTGAGCTCTTGAAGTAAATGACTTGGCCAGTCACACAGGAA 232

Qy 1872 gtcgacagacagcattttaaataagaaaataataataataatgagagtaact 1931  
 Db 231 GTGGCAGACAGCAAGCTTTTAAATGAGAAAATTAATTAATTAATGAGGTAAT 172  
 Qy 1932 taaatattataacacaaatlttaataatlaacccgtgataacacataataaa 1991  
 Db 171 TAAATATTAATTAACCAATTTTAATTAATTAATTAATTAATTAATTAATTA 112  
 Qy 1992 gttaaagataccaaaaa 2008  
 Db 111 GTTAAGATACCAAAACA 95

RESULT 10  
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 LOCUS Sequence 5359 from Patent WO0194629.  
 DEFINITION AX334850  
 ACCESSION AX334850  
 VERSION AX334850.1 GI:181255569  
 KEYWORDS  
 SOURCE human.  
 ORGANISM Homo sapiens  
 Mammalia; Eutheria; Primates; Catarrhini; Hominoidea; Homo.

REFERENCE 1 (sites)  
 Young, P.E., Augustus, M., Carter, K.C., Edner, R., Endress, G.,  
 Horrigan, S., Soppet, D.R. and Weaver, Z.  
 Cancer gene determination and therapeutic screening using signature  
 gene sets  
 Patent: WO 0194629-A 5359 13-DEC-2001;  
 Avalon Pharmaceuticals (US)  
 FEATURES  
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 Location/Qualifiers  
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Query Match 17.9%; Score 361.8; DB 6; Length 472;  
 Best Local Similarity 99.2%; Pred. No. 3.7e-73;  
 Matches 374; Conservative 0; Mismatches 2; Indels 1; Gaps 1;

Qy 1633 agcgggtggtccagatgctcttgagggtgataatgagacacagagcagcagc 1692  
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 Qy 1932 taaatattataacacaaatlttaataatlaacccgtgataacacataataa 1991  
 Db 171 TAAATATTAATTAACCAATTTTAATTAATTAATTAATTAATTAATTAATTA 112  
 Qy 1992 gttaaagataccaaaaa 2008  
 Db 111 GTTAAGATACCAAAACA 95

RESULT 11  
 AR174333/c AR174333 311 bp DNA linear PAT 17-DEC-2001  
 LOCUS Sequence 11 from patent US 630653.  
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 ACCESSION AR174333  
 VERSION AR174333.1 GI:17914653  
 KEYWORDS  
 SOURCE Unknown.  
 ORGANISM Unknown.  
 Unclassified.  
 REFERENCE 1 (bases 1 to 311)  
 Papsidero, L.D., Dyster, L.M. and Frustaci, J.M.  
 TITLE Detection and treatment of breast disease  
 JOURNAL Patent: US 630653-A 11 23-OCT-2001;  
 FEATURES  
 source 1. 311  
 Location/Qualifiers  
 /organism="unknown"  
 BASE COUNT 65 a 77 c 72 g 95 t 2 others  
 ORIGIN

Query Match 15.0%; Score 302; DB 6; Length 311;  
 Best Local Similarity 99.3%; Pred. No. 2.1e-59;  
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Qy 208 agcactacttcccatgctcctccagctgttgacagaggtttacatcatattccaga 267  
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 Db 251 GCTCTCGGAAGAGTATGATGTGCGCATGACAGAGCTGATGGGATGTGACTGGC 192  
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 Db 11 CGGC 8

RESULT 12